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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,149

01/19/2007

Mario Huesca

13198.0007U1

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23859

7590

10/29/2010

Ballard Spahr LLP

SUITE 1000

999 PEACHTREE STREET

ATLANTA, GA 30309-3915

EXAMINER

KLINKEL, KORTNEY L

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

10/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,149	Applicant(s) HUESCA ET AL.	
	Examiner Kortney L. Klinkel	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-45 is/are pending in the application.
- 4a) Of the above claim(s) 23, 28-38 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2, 21, 22, 24, 39-43 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

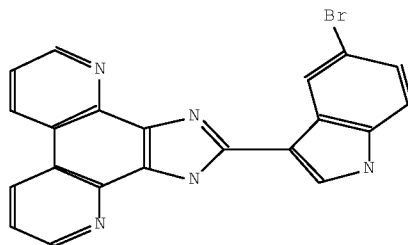
Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the remarks/amendments filed 7/8/2010. Claims 1-20 stand canceled. Claims 21-45 are pending. Claims 21-22, 26, 33 and 37-44 have been amended. Claims 23, 28-38 and 44 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Claims 21-22, 24-27, 39-43 and 45 are currently under consideration to the extent that they read on the elected species, namely the compound of claim 39. Please note also that examination of all 112 1st issues such as enablement and written description, of the claims have been limited to the elected species only.

Please note that in searching for the elected species, the compound of claim 38, the Examiner found art which reads on the broader scope of compounds claimed. In an effort to expedite prosecution, this art has been applied. Accordingly, the elected species has been expanded to include the following species:



Claims 21-22, 24-27, 39-43 and 45 have been examined to the extent that they read on the elected species, the compound of claim 38 and the above brominated species.

Priority

The following was originally stated in the Office action dated 12/8/2008 and is restated here for convenience:

Acknowledgement is made that the instant application is a 371 of PCT/IB04/52433 filed 11/15/2004, which claims benefit of 60/520279 filed 11/14/2003 and claims benefit of 60/599509 filed 8/6/2004. Note is made that the elected species, compound 90, page 38 of the specification, also the compound of instant claim 39, has support back to the earliest filed provisional application, 60/520279 filed 11/14/2003.

Claim Rejections - 35 USC § 112—Withdrawn

The rejection of claims 21-22, 24-25, 27, and 40-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the claim amendments to change alkoxy to methoxy in the definition of R10.

Claim Rejections - 35 USC § 102

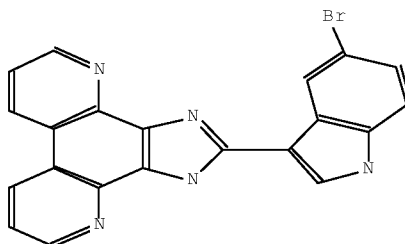
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-22, 24-27, 39-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Dora et al. ("Synthesis of Some Fused 2-Arylimidazoles and their Derivatives" J. Indian Chem. Soc. LVI, 1979, 620-624).

Dora et al. teaches the following compound, see compound IV i and the discussion immediately preceding Table 1:



This compound is the result of reacting a compound of formula IV (p. 620) with 5-bromo indole-3-carboxylic aldehyde (see “i” at the bottom of Table 1) in a simple condensation reaction.

Response to Arguments

Applicant's arguments submitted 7/8/2010 have been fully considered, but are not persuasive. Applicant argues that contrary to the Office Action's assertion and as show in Scheme 2 on page 620 of Dora et al. that the compound formed by the condensation of diketone IV and aldehyde (i) comprises a hydroxyl substituent on the imidazole ring. Applicant argues that the currently amended set of claims exclude hydroxyl from this position (the R4 position). This argument is not persuasive.

Dora et al. teaches both imidazole containing compounds as well as 1-hydroxy imidazole derivatives. Scheme 1 (p. 620) is directed to the formation of imidazole derivatives which are shown in Table 1. Note that Table 1 is titled “Physical data on imidazole derivatives) whereas table 3 is titled “Physical data on 1-hydroxy-imidazoles”. Scheme 2 (p. 620), on the other hand is directed to the formation of 1-hydroxyl-imidazole-3-oxide derivatives as well as to the reduced form 1-hydroxyl imidazole

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derivatives. Data for the 1-hydroxyl-imidazole-3-oxide derivatives is shown in Table 2 (p. 621) and data for the 1-hydroxyl imidazole derivatives is shown in Table 3 (p. 622, see also compound VI). Please note that the reaction of Scheme 1 utilizes NH_2OAc rather than NH_2OH as in Scheme 2. These different reagents yield the 1-H imidazole derivatives and the 1-hydroxyl imidazole derivatives respectively. Additional support for this fact stems from the Experimental section of Dora et al. at page 623. This section details the synthesis of compound IV (c), a 1-H imidazole derivative, which is an analogous compound to compound IV (i) formed by the condensation of phanquone IV with p-chloro benzaldehyde (c) rather than 5-bromoindole-3-carboxylic aldehyde (i). Please note further that the Experimental section also details the synthesis of the 1-hydroxyl imidazole derivative formed with p-chloro benzaldehyde. The 1-hydroxyl imidazole compound is formed using the reagent NH_2OH (ammonium hydroxide) rather than NH_2OAc (ammonium acetate) which is the reagent used in forming the 1-H imidazole derivative. Accordingly it is clear that compound VI (i) of Table 1 is the 1-H imidazole derivative rather than the 1-hydroxyl imidazole derivative, the structure of which anticipates the claims as discussed in the above rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

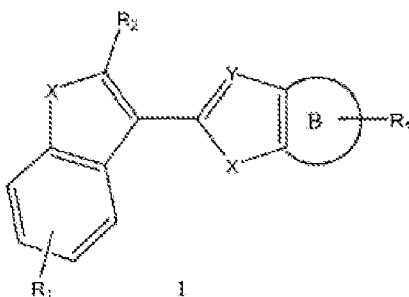
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22, 24-27, 39-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bannister et al. (WO 2000/78761).

Bannister teaches compounds of the following general formula which have utility as antibacterial/antiinfective agents.



Wherein X can be NH, Y can be N, R₂ can be Me, R₁ need not be present and B can be a polycyclic cycloalkyl or heteroaryl, or heterocyclic rings *inter alia* (page 18, also claims 1-20, particularly claim 2 and 7-10 wherein B is a fused aromatic or heteroaromatic ring). Pages 10-11 of the disclosure further define the term heterocyclyl or heterocyclic group to mean phenanthroline.

Bannister teaches several examples wherein R₂ is Me, X is NH, Y is N and R₁ is absent. Bannister fails to teach a specific embodiment wherein B is phenanthroline. However, phenanthroline is suggested as a possible B ring from a finite number of possible combinations. Whereas it is true that such “picking and choosing” within several variables does not necessarily give rise to anticipation, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under

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35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is...a person of ordinary creativity, not an automaton.” *Id.* at 1742. Consistent with this reasoning, it would have obvious to have arrived at the instantly claimed compounds and specifically the elected species, which is the compound of claim 39 having a fused phenanthroline ring, as compounds having this functionality were suggested by Bannister as a possible option. From the teachings of Bannister, it would have been obvious to one of ordinary skill in the art at the time of the instant invention, to arrive at the elected species with a reasonable expectation that the resulting compound would have utility as an antibacterial/antiinfective agent. One would have been motivated to do so because the elected compound is suggested from a finite number of possible combinations. The indiscriminate selection of "some" among "many" is *prima facie* obvious. See *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

Response to Arguments

Applicant's arguments filed 7/8/2010 in response to the rejection of claims over Bannister have been fully considered, but are not persuasive.

Applicant maintains the argument that the Examiner failed to present a *prima facie* case of obviousness. Applicant argues that the rejection is improper because the Examiner failed to identify a known lead compound and that the Examiner therefore

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also failed to provide the reasoning that would lead one of ordinary skill in the art to modify the lead compound in a way that would have resulted in the claimed compounds. Applicant again points to *Takeda Chem. Indus., Ltd. v. Aphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007) for support of these requirements and argues that the Examiner's interpretation of *Takeda* in the Office action mailed 1/8/2010 are in error and that an obviousness allegation based on structural similarity between claimed and prior art compounds "clearly depends on a preliminary finding that one of ordinary skill in the art would have selected [the prior art compound] as a lead compound." *Takeda*, at 1359. Applicant also points to *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 553 F.3d 1353 (Fed. Cir. 2008 ("*Eisai*") at 1359 stating that "post-KSR, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound" in the prior art and further stating that "[o]bviousness based on structural similarity thus can be proved by identification of some motivation that would have lead one of ordinary skill in the art to select and then modify a known compound in a particular way to achieve the claimed compound. These arguments are not persuasive.

Upon closer scrutiny of the *Takeda* case, the Examiner agrees with Applicant that her discussion of *Takeda* in the previous Office action was in error when she stated that "the *Takeda* case dealt with methods of treatment with the compounds at issue whereas the instant claims, as elected, are directed to simply compounds." However, the point the Examiner was attempting to make with this analysis, is that the fact pattern of *Takeda* as well as *Eisai* for that matter, differ from the facts in the present

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obviousness rejection. In *Takeda* the courts ruled that the claimed compound would not have been obvious because the prior art reference taught away from using the lead compound in question. Because of this, the courts ruled that there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound. Likewise in *Eisai*, the courts ruled that the claimed compound would not have been obvious because there was no reason to modify the lead compound to arrive at the claimed compound because the prior art taught that modifying the lead compound would destroy its advantageous property. The instant situation differs from the situations of *Takeda* and *Eisai* in that the prior art reference Bannister et al. teaches a generic set of compounds useful as antibacterials/antiinfectives which encompass the elected species of compound. One of ordinary skill in the art would therefore have the reasonable expectation that any and all compounds falling within the disclosed genus would be useful as antibacterials/antiinfectives. This was not the case in either *Takeda* or *Eisai*. The instant rejection is based on the fact that the prior art reference Bannister et al. discloses compounds of formula 1 (see page 18; also claims 1, 2 and 7-10 for a smaller subgenus of compounds). Bannister teaches several examples wherein R_2 is Me, X is NH, Y is N and R_1 is absent. Bannister fails to teach a specific embodiment wherein B is phenanthroline. As applicant points out in the arguments at page 50, second full paragraph, all of the exemplified compounds of Bannister et al. have B equal to a phenyl ring rather than the claimed 1,10-phenanthroline ring. However, disclosed examples and preferred embodiments do not constitute a teaching away from a broader

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disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). To this effect, as is addressed in the above rejection, Bannister et al. teach that B can be a heteroaryl ring (p. 18) or more specifically a phenanthroline ring (p. 11, line 1) and teach that R1 and R2 can be H and Me respectively. As such it would be obvious to substitute with the reasonable expectation that an antibacterial would result. Again it is highlighted, that unlike in Takeda, the prior art reference at hand does not teach or suggest that such a substitution would be detrimental to the resulting activity of the compound. Again it is noted that applicant has not provided evidence to the contrary.

Applicant also argues that the only reason given by the Office Action for arriving at the elected compound is that it is a possibility from the finite number of possible combinations in the general formula of Bannister and further that the number of possible permutations encompassed by the definitions provided by Bannister et al. are vast and as such the Examiner's assertion that this vast number of possible permutations is a finite number is erroneous. These arguments are not persuasive.

The Applicant's arguments may be persuasive if one were working in a complete vacuum and had nothing to go off in order to arrive at the instantly claimed compound. However, such is not the case. As outlined in the above rejection and highlighted above, Bannister et al. discloses compounds of formula 1 (see page 18; also claims 1, 2 and 7-10 for a smaller subgenus of compounds), the generic formula of which encompasses the elected compound. Bannister teaches several examples wherein R₂ is Me, X is NH, Y is N and R₁ is absent. Bannister fails to teach a specific embodiment

wherein B is phenanthroline. Additionally, Bannister teaches at page 17, lines 15-23:

Contemplated equivalents of the compounds described above include compounds which otherwise correspond thereto, and which have the same general properties thereof (e.g., functioning as analgesics), wherein one or more simple variations of substituents are made which do not adversely affect the efficacy of the compound in binding to opioid receptors. In general, the compounds of the present invention may be prepared by the methods illustrated in the general reaction schemes as, for example, described below, or by modifications thereof, using readily available starting materials, reagents and conventional synthesis procedures. In these reactions, it is also possible to make use of variants which are in themselves known, but are not mentioned here.

Page 48 describes a detailed synthetic procedure for preparing the compounds. As discussed at page 17, arriving at the elected species would merely require the judicious selection of a phenanthroline-based diamine (B) and the appropriate indol-aldehyde (A). As the instantly claimed elected species does not contain any functionality that would interfere with this simple condensation reaction, one of ordinary skill in the chemical arts would be expected to synthesize the elected species with little trouble. Unlike a vacuum, Bannister et al. provides one of ordinary skill in the art the necessary tools necessary to arrive at the elected compound. Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is...a person of ordinary creativity, not an automaton.” *Id.* at 1742. Consistent with this reasoning, it would have been obvious to have arrived

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at the instantly claimed compounds and specifically the elected species, which is the compound of claim 39 having a fused phenanthroline ring, as compounds having this functionality were suggested by Bannister as a possible option and Bannister provides a teaching of the intermediate pieces and a method necessary to synthesize the desired compound.

Applicant argues that it appears as if the definition of success used by the Office Action in the rejection is that the compound can be made, without regard to any purpose or utility. Applicant argues that this is not what the courts mean by a reasonable expectation of success and points to *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal Inc.* 231 F.3d 1339, 1345 (Fed. Cir. 2000) and *Eisai* at 1357. Applicant also points to *Takeda* and argues that the Federal Circuit took into account the ultimate use of the compounds when considering the requirements for a lead compound (*Takeda* at 1357). Applicant argues that in both *Takeda* and *Eisai* the prior art compounds at issue had the same ultimate use which is not the case here and that the Federal Circuit despite this fact still found the claims to be unobvious over the art. Applicant notes that in the context of Bannister, a meaningful success would have to take account of the established purpose of the described compounds as antimicrobial agents whereas in the context of the presently claimed compounds, a meaningful success must take account of the established purpose of the compounds as anti-cancer agents, which is neither taught nor suggested by Bannister. These arguments are not persuasive.

The above rejection as well as the response dated 1/8/2010 address the issue of a reasonable expectation of success. In short, given the teachings of Bannister et al.

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the skilled artisan would expect any and all of the compounds falling within the genus described by formula 1 to have utility as an antibacterial/antiinfective. As the elected compound is made obvious by this teaching (see above rejection and discussion), one would expect the elected species to have utility as an antimicrobial agent. Again applicant is reminded that their **claims** are all directed to compounds or a pharmaceutical composition comprising the compound of claim 21 in the case of claim 27. The intended ultimate use of these compounds as disclosed in the **specification** is as anti-cancer agents. Accordingly the fact that the prior art suggests a different utility for the claimed compounds/compositions is immaterial as the claims do not even recite a future intended use. However, even if the claims did set for the future intended use as an anti-cancer agent, this ultimate intended use a compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant situation, there is nothing from the disclosure of Bannister which would prevent the compounds taught therein from being used as anti-cancer agents. In fact, page 3 of Bannister line 31 teaches that the disclosed compounds can be incorporated into pharmaceutical preparations to be administered for inhibiting the growth of bacterial microorganisms. In sum, the instant claims are directed to compounds which the teachings of Bannister make obvious.

Further, applicant argues that a reasonable expectation of success is not provided by the teachings of Bannister et al. even when meaningful success is limited to

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achieving the anti-microbial purpose described in Bannister. Applicant points to a compound disclosed in Figure 7 of Bannister that has an MIC < 1 μ g/mL and refers to this compound as a lead compound as it would require the least number of chemical transformations to arrive at the elected species. Applicant argues that Bannister shows that substitution of one of the chlorines on the benzimidazole ring with a larger methyl ester results in a significant decrease in activity. Accordingly applicant concludes that one would not think to replace the dichlorophenyl group with the much larger phenanthroline ring or phenanthrene ring since the less sterically drastic replacement with a chloro-methylester-phenyl resulted in greatly decreased activity. Applicant cites *In re O'Farrell*, 853 F.2d 894, 903-04, (Fed. Cir. 1988) ("There can be little better evidence negating an expectation of success than actual reports of failure."). These arguments are not persuasive.

First, applicant's analysis and conclusion that the resulting antimicrobial activity is inversely related to sterics is flawed. This analysis conveniently ignores all the other factors/properties, such as electronics and solubility as just two examples, involved in substituting a chloride with a methyl ester. Given the data provided by Bannister et al., one cannot conclude that activity is directly related to sterics. Even so, the fact remains that the less active methyl ester derivative is still active as an antimicrobial, which is what the overall teachings of Bannister suggest, just as the overall teachings of Bannister suggest that the elected compound would also have utility as an antimicrobial.

Applicant also argues that the exclusive use of the benzimidazolyl moiety does not suggest that the skilled artisan could, with a reasonable expectation of meaningful

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success replace it with a phenanthroline or phenanthrene ring structure. Applicant also argues that all the examples of Bannister have either a chlorine or a bromine on the indole ring and that all examples lack a methyl group on the indole ring. Applicant concludes that therefore there is no suggestion to make the claimed elected compound. This argument is not persuasive. As addressed earlier, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). To this effect, as is addressed in the above rejection, Bannister et al. teach that B can be a heteroaryl ring (p. 18) or more specifically a phenanthroline ring (p. 11, line 1) and teach that R1 and R2 can be H and Me respectively. As such it would be obvious to substitute with the reasonable expectation that an antibacterial would result. Again it is highlighted, that unlike in *Takeda*, the prior art reference at hand does not teach or suggest that such a substitution would be detrimental to the resulting activity of the compound. Applicant has not provided evidence suggesting that the reasonable expectation gleaned from Bannister, which is that the compounds would exhibit antimicrobial activity, is in error.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-22, 24-27, 39-43 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-26, 42-43, 45, 74, 79, 81, 83, 87, 89, 91, 93, 95, and 98-99 of copending Application No. 10/525690 (note that the claim numbers and below rejection have been modified to address the amendments to copending claims in application '690). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a compound of formula VI and the co-pending claims of application '690 are also drawn to a compound of formula VI. The definitions of substituents of these two formulae overlap significantly and only vary in a few instances (i.e. the instant R6 is slightly more limited than R6 of co-pending '690). Claims 25-26 generically encompass the elected species of the instant application. Compound 44, first compound of claim 74 is the instantly elected species. It would be obvious to arrive at the elected species, as it is suggested from a finite listing of possible combinations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-22, 24-27, 39-43 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43-74 of copending Application No. 11/915257. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a compound of formula VI and the co-pending claims of application '257 are drawn to compounds of formula I, which have a phenanthroline backbone and anticipate the compounds of instant formula IV. The definitions of substituents of the compounds of formula I completely fall within those definitions instantly presented for formula IV. The claims of application '257 recite various intended uses. However, a recitation of the intended use of a compound must result in a structural difference between the claimed invention, absent this difference, the compounds of application '257 and the instant compounds are indistinguishable. Please note that method claims 57-74 utilize the claimed compounds and thereby also read on the instant compound claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

In the response filed 7/8/2010 applicant acknowledges the double patenting rejections and requests that the rejections be held in abeyance until an indication that the claims are otherwise allowable. As no arguments regarding the merits of the

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rejections have been presented, the double patenting rejections over co-pending applications 10/525690 and 11/915257 are maintained.

Conclusion

Claims 21-22, 24-27, 39-43 and 45 are rejected. No claim is allowed.

No new ground(s) of rejection were presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 10 am to 7 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Ashwin Mehta/
Primary Examiner, Technology Center 1600